Ferritin

infinosis™

Ferritin (FIA)

REF: IN067706 Σ 25

Intended use
The infinosis™ Ferritin is a fluorescence immunoassay for the in vitro quantitative determination of Ferritin in Human whole blood, serum or plasma. For professional use only.

Summary
References[1-6]
Ferritin is a macromolecule with a molecular weight of at least 440 kD (depending on the iron content) and consists of a protein shell (apoferritin) of 24 subunits and an iron core containing an average of approx. 2500 Fe^{3+} ions (in liver and spleen ferritin). Ferritin tends to form oligomers, and when it is present in excess in the cells of the storage organs there is a tendency for condensation to semicrystalline hemosiderin to occur in the lysosomes. At least 20 isoferritins can be distinguished with the aid of isoelectric focusing. This microheterogeneity is due to differences in the contents of the acidic H and weakly basic L subunits. The basic isoferritins are responsible for the long-term iron storage function, and are found mainly in the liver, spleen, and bone marrow. They have a lower iron content and presumably function as intermediaries for the transfer of iron in various syntheses The determination of ferritin is a suitable method for ascertaining the iron metabolism situation. Determination of ferritin at the beginning of therapy provides a representative measure of the body's iron reserves. A storage deficiency in the reticulo-endothelial system (RES) can be detected at a very early stage. Clinically, a threshold value of 20 µg/L (ng/mL) has proved useful in the detection of prelatent iron deficiency. This value provides a reliable indication of exhaustion of the iron reserves that can be mobilized for hemoglobin synthesis. Latent iron deficiency is defined as a fall below the 12 µg/L (ng/mL) ferritin threshold. These two values necessitate no further laboratory elucidation, even when the blood picture is still morphologically normal. If the depressed ferritin level is accompanied by hypochromic, microcytal anemia, then manifest iron deficiency is present. When the ferritin level is elevated and the possibility of a distribution disorder can be ruled out, this is a manifestation of iron overloading in the body. 400 µg/L (ng/mL) ferritin is used as the threshold value.

Test principle
Sandwich principle. Total duration of assay: **15 minutes**
Sample is added to the sample well of the test, then the fluorescence-labeled detector anti-Ferritin antibody binds to Ferritin antigen in blood specimen. As the sample mixture migrates on the nitrocellulose matrix of test strip by capillary action, the complexes of detector antibody and Ferritin are captured to anti-Ferritin antibody that has been immobilized on test strip.
The more Ferritin antigen is in blood specimen, the more complexes are accumulated on test strip. Signal intensity of fluorescence of detector antibody reflects amount of Ferritin captured and instrument for infinosis™ tests shows Ferritin concentrations in blood specimen.

Reagents
Materials provided
- **Test Cartridge**, 25 pcs, individually packaged
- **ID Chip** or **QR code of Calibration Curve**, 1 pcs
- **Sample Buffer,** 25 tubes
- **IFU**, 1 copy

Materials required (but not provided)
- infinosis™ FIA analyzer
- Ferritin control (DiaSino control is recommended)
- Transfer pipette set (100 µL size)
- Centrifuge (for plasma and serum only)
- Timer

Precautions and warnings
- For in vitro diagnostic use only.
- Carefully follow the instructions and procedures described in this instructions before testing.
- The test cartridge should remain in its original sealed pouch until ready to use. Do not use it if the pouch is damaged or the seal is broken.
- Do not use reagents beyond the labeled expiry date.
- Do not mix or use components from kits with different Lots.
- Don't use Test Cartridge if its Lot does not match with ID Chip that is inserted onto the instrument.
- The infinosis™ Ferritin should be used only in conjunction with the instrument for infinosis™ tests.
- The tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample is taken by qualified medical personnel.
- infinosis™ Ferritin assay is single use only. Do not reuse it.
- The Test Cartridge and instrument for infinosis™ tests should be used away from vibration and magnetic field. During normal usage, the Test Cartridge may generate slight vibration, which should be regarded as normal.
- Use separate clean pipette tips and buffer tubes for different specimens. The pipette tips and detector buffer tubes should be used for one specimen only.
- Do not smoke, eat, or drink in areas in which specimens or kit reagents are handled.
- Blood specimens, used test cartridges, pipette tips and sample buffer tubes are potentially infectious. Proper laboratory safety techniques, handing and disposal methods should be followed in accordance with standard procedures and relevant regulations observed by microbiological hazard materials.
- The results should be interpreted by the physician along with clinical findings and other laboratory test results.

Incident report
Any suspected serious incidents related to this assay shall be immediately reported to DiaSino, DiaSino's Authorized Representative in the EU, and the national competent authorities of the Member States where the users and/or patients are located.

Storage and stability
- Store the test kit at 2-30°C, the stability is up to the expiration date printed on package.
- Test cartridge and sample buffer should be used within 1 hour after opening the pack.

Specimen collection and preparation
- The test can be performed with either Human serum, plasma or whole blood.
- Collect serum samples in accordance with correct medical practices.
- Using standard phlebotomy procedure, collect a venipuncture whole blood specimen using a blood collection tube. If collecting plasma use a blood collection tube containing suitable anticoagulant (EDTA recommended).
- Separate the serum/plasma from blood as soon as possible to avoid hemolysis.
- Test should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C.

Quality control
- Quality control tests are a part of the good testing practice to confirm the expected results and validity of the assay and should be performed at regular intervals.
- The control tests should be performed immediately after opening a new test lot to ensure the test performance is not altered.
- Quality control tests should also be performed whenever there is any question concerning the validity of the test results.
- Control materials are provided on demand with infinosis™ tests. For more information regarding obtaining the control materials, contact DiaSino Laboratories Co., Ltd for assistance.

Test setup
- Ensure that the lot number of the cartridge matches that of the sample buffer, and the ID Chip.
- If the sealed cartridge and sample buffer have been stored in refrigerator, place them at room temperature (18-25 °C) at least 30 minutes before measurement.
- Turn on the instrument for infinosis™ tests.
  Refer to the *'instrument for infinosis™ tests Operation Manual'* for the complete information and operating instructions.

Test procedure
1. Insert ID Chip into the instrument for infinosis™ tests or Scan the QR code to read the calibration curve.
2. Using a pipette to transfer **20 µL** of sample (Human plasma/serum/whole blood) to the **sample buffer tube** provided in the kit.
3. Close the lid of the sample mixing tube and mix the sample thoroughly for **5-10 seconds** by tapping or inverting the tube.
4. Pipette out **100 µL** of **sample mixture** and load it onto the sample well on the cartridge.

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5. Leave the sample-loaded cartridge at room temperature for **15 minutes.**
6. Insert the sample-loaded cartridge into the cartridge holder of instrument for infinosis™ tests.
   Ensure proper orientation of the cartridge before pushing it all the way inside the cartridge holder.
7. Press **"Test"** button on the instrument for infinosis™ tests.
8. Instrument for infinosis™ tests will start scanning the sample-loaded cartridge immediately.
9. Read the test result on the display screen of the instrument for infinosis™ tests.
10. Print out the testing results when press **"Print"** button on the instrument for infinosis™ tests.

Limitations - interference

- The assay is unaffected by icterus (bilirubin < 1112 µmol/L or < 65 mg/dL), hemolysis (Hb < 0.31 mmol/L or < 0.5 g/dL), lipemia (Intralipid < 3300 mg/dL) and biotin (< 205 nmol/L or < 50 ng/mL).
- Criterion: Recovery within ± 10 % of initial value.
- Samples should not be taken from patients receiving therapy with high biotin doses (i.e. > 5 mg/day) until at least 8 hours following the last biotin administration.
- No interference was observed from rheumatoid factors up to a concentration of 2500 IU/mL.
- There is no high-dose hook effect at ferritin concentrations of up to 50000 µg/L (ng/mL).
- No interference with the assay was found.
- Iron2+- and iron3+-ions at therapeutic concentrations do not interfere with the DiaSino Ferritin assay.
- In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.
- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Measuring range

2.0-1000 ng/mL (defined by the lower detection limit and the maximum of the master curve). Values below the lower detection limit are reported as < 8.0 ng/mL. Values above the measuring range are reported as > 1000 ng/mL.

Lower detection limit

2.0 ng/mL

The detection limit represents the lowest analyte level that can be distinguished from zero. It is calculated as the value lying two standard deviations above that of the lowest standard (master calibrator, standard 1 + 2 SD, repeatability study, n = 21).

Expected values

Men, 18-60 years	27 - 430 µg/L(ng/mL)
Women, 18-60 years	15-168 µg/L (ng/mL)

Each laboratory must establish its own normal ranges based on patient population.The values correspond to the 2.5th and 97.5th percentiles of results obtained from a total of 869 healthy test subjects examined as below:

Specific performance data

Representative performance data are given below. Results obtained in individual laboratories may differ.

Precision

Intra-assay

Determined by by using 10 replicates from same batch to test with 500 ng/mL Ferritin control. CV ≤ 10%.

Inter-assay

Determined by using 3 replicates from random 3 continuous batches to test with 500 ng/mL Ferritin control CV ≤ 15%.

Linearity

A serial concentration of Ferritin controls at 10 ng/mL, 20 ng/mL and 50 ng/mL, 100 ng/mL, 150 ng/mL, 200 ng/mL were tested, the Correlation Coefficient is r ≥ 0.9912.

Method comparison

A comparison of the infinosis™ Ferritin assay (y) with the Roche Elecsys Ferritin assay (x) using 119 clinical samples gave the correlation: r=0.9620

Analytical specificity

Human liver ferritin 98% recovery
Human spleen ferritin 90% recovery
Human heart ferritin 1.0% recovery

Functional sensitivity

2.50 ng/mL

The functional sensitivity is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

References

1. Wick M, Pinggera W, Lehmann P. Ferritin in Iron Metabolism - Diagnosis of Anemieas (second edition). Springer-Verlag 1995;ISBN 3-211-82525-8 and ISBN 0-387-82525-8.
2. Arosio P, Levi S, Gabri E, et al. Heterogeneity of ferritin II: Immunological aspects. In: Albertini A, Arosio P, Chiancone E, Drysdale J (eds). Ferritins and isoferritins as biochemical markers. Elsevier, Amsterdam 1984;33-47.
3. Kaltwasser JP, Werner E. Serumferritin: Methodische und Klinische Aspekte. Springer Verlag (1980).
4. Morikawa K, Oseko F, Morikawa S. A role for ferritin in hematopoiesis and the immune system. Leuk-Lymphoma 1995;18(5-6):429-433.
5. Borch-lohnson B. Determination of Iron status: brief review of physiological effects on iron measures. Analyst 1995;120(3):891-903.
6. Cook-JD, Skikne-BS, Baynes RD. Iron deficiency: the global perspective. Adv-Exp-Med-Biol 1994;356:219-228.

Symbols

IVD In vitro diagnostic medical device	30°C / 2°C Temperature limit	Consult instructions for use	REF Catalog number
LOT Batch code	Date of manufacture	Use-by date	Contains sufficient for <n> tests
Manufacturer	Do not re-use	Do not use if package is damaged and consult instructions for use	European Conformity
EC REP Authorized representative in the European Community			

diasino

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